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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/682,546	10/10/2003	K. M. Slimak	TPP 31413DIV	9719

7590 09/27/2007
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EXAMINER

WINSTON, RANDALL O

ART UNIT	PAPER NUMBER
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1655

MAIL DATE	DELIVERY MODE
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09/27/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/682,546	SLIMAK, K. M.	
	Examiner	Art Unit	
	Randall Winston	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 February 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-7 and 9-20 is/are pending in the application.
- 4a) Of the above claim(s) 15 and 16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-2,4-7,9-14 and 17-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Acknowledgement is made of receipt and entry of the amendment filed on 07/23/2007.

Examiner's 1122nd, second paragraph, rejection has been overcome by Applicant's amendment.

Readable claims 1-2,4-7,9-14 and 17-20 will be examined on the merits. Claims 15 and 16 have been withdrawn from consideration.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-2,4-7, 9-14 and 17-20 as amended still stand rejected under 35 U.S.C. 112, first paragraph because the specification, while being enabled for a method for a dietary intervention of treating particular conditions and symptoms in animals, including humans (i.e. Applicant is enabled for treating the particular conditions and symptoms recited in claim 1 of Application No. 09/889,133 issued as U.S. Patent No. 6,632,461. Also please note Application 10/682,546 being a divisional of parent application 09/889,133) selected from the group consisting of autism, anxiety, arthritis, asthma, colic, congestion, diabetes, digestive upsets, irritable bowel syndrome, eczema, fatigue, migraine headaches, multiple sclerosis, seizures and rashes comprising a) withholding all food for at least 5 days, except for tropical root crops b) and feeding a concentrated form of tropical root crops selected from

the group consisting of white sweet potato, malanga, cassava, true yam, water chestnut, arrowroot, and lotus for a period of at least five days to said patient (as recited in claim 1 of US 6,632,461), the specification does not enable any person in the art in preparing a method for a dietary intervention of treating any and/or all chronic diseases, conditions and symptoms comprising a) withholding all food for at least 5 days, except for tropical root crops b) and feeding a concentrated form of any and/or all tropical root for a period of at least five days to said patient.

In Applicants' response on 07/23/2007, Applicants' argues it is the Applicant, not the Examiner, who determines what the Applicant regards as the invention and having regard for the invention as a method for dietary intervention, the Examiner is powerless to make an argument redefining the invention as treating certain diseases, conditions and symptoms.

Applicants' argument is not found persuasive because claims 1-2,4-7, 9-14 and 17-20 still stand rejected under 35 U.S.C. 112, first paragraph, for the same reasons set forth in examiner's non-final office action of 02/23/2007. Although Applicants' argue the Examiner is powerless to make an argument redefining the invention as treating certain diseases, conditions and symptoms, Applicants' argument is not found persuasive because Examiner is only redefining what Applicants' are enabled for. According to Applicants' specification, Applicants' are enabled for a method for a dietary intervention of treating particular conditions and symptoms in animals, including humans

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selected from the group consisting of autism, anxiety, arthritis, asthma, colic, congestion, diabetes, digestive upsets, irritable bowel syndrome, eczema, fatigue, migraine headaches, multiple sclerosis, seizures and rashes comprising a) withholding all food for at least 5 days, except for tropical root crops b) and feeding a concentrated form of tropical root crops selected from the group consisting of white sweet potato, malanga, cassava, true yam, water chestnut, arrowroot, and lotus for a period of at least five days to said patient.

The factors to be considered in determining whether undue experimentation is required are summarized in *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) (a) the breadth of the claims; (b) the nature of the invention; © the state of the prior art; (d) the level of one of ordinary skill; (e) the level of predictability in the art; (f) the amount of direction provided by the inventor; (g) the existence of working examples; and (h) the quantity of experimentation needed to make or use the invention based on the content of the disclosure.

Applicant claims a method for a dietary intervention of treating any and/or all chronic diseases, conditions and symptoms comprising a) withholding all food for at least 5 days, except for tropical root crops b) and feeding a concentrated form of any and/or all tropical root for a period of at least five days to said patient. Applicant has reasonably demonstrated on pages 51-54, examples III-VI of the specification, a method for a dietary intervention of treating particular conditions and symptoms in animals,

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including humans selected from the group consisting of autism, anxiety, arthritis, asthma, colic, congestion, diabetes, digestive upsets, irritable bowel syndrome, eczema, fatigue, migraine headaches, multiple sclerosis, seizures and rashes comprising a) withholding all food for at least 5 days, except for tropical root crops b) and feeding a concentrated form of tropical root crops selected from the group consisting of white sweet potato, malanga, cassava, true yam, water chestnut, arrowroot, and lotus for a period of at least five days to said patient. Applicant's specification, however, has failed to provide guidance or working examples whereby applicant prepares a method for a dietary intervention of treating any and/or all chronic diseases, conditions and symptoms comprising a) withholding all food for at least 5 days, except for tropical root crops b) and feeding a concentrated form of any and/or all tropical root for a period of at least five days to said patient

Moreover, it should be noted that the state of the prior art at the time the invention was filed did not recognize a method for a dietary intervention of treating any and/or all chronic diseases, conditions and symptoms comprising a) withholding all food for at least 5 days, except for tropical root crops b) and feeding a concentrated form of any and/or all tropical root for a period of at least five days to said patient. For example, Slimak et al. et al. teach (US 5789012 see, e.g. title, column 2, lines 33-35) feeding tropical root crops selected from the group consisting of sweet potatoes, cassava, edible aroids, amaranth, yams lotus and potatoes to treat conditions such as food allergies. Thus, the art is silent regarding the efficacy of applicant's method for a dietary

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intervention of treating any and/or all chronic diseases, conditions and symptoms comprising a) withholding all food for at least 5 days, except for tropical root crops b) and feeding a concentrated form of any and/or all tropical root for a period of at least five days to said patient. Therefore, applicant's claimed method is highly unpredictable in the art. In addition, the applicant's specification fails to provide guidance or working examples whereby applicant prepares a method for a dietary intervention of treating any and/or all chronic diseases, conditions and symptoms comprising a) withholding all food for at least 5 days, except for tropical root crops b) and feeding a concentrated form of any and/or all tropical root for a period of at least five days to said patient.

Therefore, it would require undue experimentation without a reasonable expectation of success for one of skill in the art to practice the invention commensurate in scope with the claims.

No claims are allowed.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Randall Winston whose telephone number is 571-272-0972. The examiner can normally be reached on 8AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



CHRISTOPHER R. TATE
PRIMARY EXAMINER